



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,628	03/16/2007	Carsten Andersen	12684.0020FPWO	9476
23552 7590 07/05/2011				
MERCHANT & GOULD PC				
P.O. BOX 2903				
MINNEAPOLIS, MN 55402-0903				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
07/05/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/581,628

Applicant(s)

ANDERSEN, CARSTEN

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/26/2011 has been entered. No new claims have been added.

Applicant's arguments filed 05/26/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 22-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the limitation "reaction product" which renders the claims indefinite. Where the product of such a reaction will vary and thus be determined by reaction conditions, proportions of reactants, etc., the term is indefinite without a concurrent recitation of the specific conditions used. In re Wohnseidler, 137 USPQ 336 (C.C.P.A. 1963).

Claim Rejections - 35 USC § 103

Claims 1-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walling (US 6,586,449) in view of Ferno et al. (US 3,845,217).

Applicant argues that a declaration has been presented by Carsten Andersen which declares that the USP method used to measure the release rates in Walling et al. is identical to the method used by Applicant; that the instant claimed product and method produced an average release rate of 81.7% for Example A, 80.2% for Example B, and 78.6% for commercial full scale batches; that release rates of 80% or greater is unexpected and surprising; that Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine; and that there is not teaching or suggestion in Ferno or Walling that adding more nicotine to the resin would enhanced the rate of nicotine release from the resin. Applicant argues that the amount of nicotine in the Walling product is at least 50% greater than the amount disclosed in Ferno, so there is not motivation to mix the nicotine with the exchange resin prior to addition of the polyol.

The Examiner disagrees.

The data obtained from the Examples does not appear to support the allegation of unexpected results, since the results for the full scale commercial batches do not produce the claimed release rates. Based on the results, the commercial product would not produce a release rate of at least 80%. Therefore, due to the variation in the results, i.e. release rates are produced that are greater than 80% and that are less than 80%, it is uncertain whether the methods of the instant invention as claimed provide the alleged unexpected results. Further, no support has been provided that establishes that the results obtained from the commercial batches, i.e. 78.6% release rate, represents a statistically significant difference from the 71% release rate of Walling et al. as to be considered unexpected. Accordingly, as cited in MPEP 2144.04, IV, C, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. Further, Ferno et al. is only provided as prior art to disclose that the release rate of nicotine from a composition can be varied by varying the amount of nicotine which is bound to a given quantity of cation exchanger, and that a relatively higher amount of nicotine present gives a quicker release, and not for any particular composition (column 3, lines 69-75). The addition of the nicotine directly to the cation exchange resin would be expected to bind nicotine to available exchange sites before the addition of polyol. Accordingly, the skilled artisan would be motivated to at least try to combine the nicotine and cation exchange resin with a reasonable expectation that a larger amount of nicotine would be bound to the exchange resin and provide a quicker release. It would have been within the purview of the skilled artisan to determine both

the amount of nicotine bound to the resin and the resulting release rate provided by the nicotine/exchange resin combination since Walling et al. provide methods for such measurements.

Double Patenting

Claims 1-24 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 6, 10-15 and 19-22 of copending Application No. 11/921199.

Applicant requests that the rejection be held in abeyance until allowable subject matter is indicated.

This rejection is maintained since applicant does not argue the merits of the rejection; and neither allowable subject matter has been indicated, nor has a terminal disclaimer been filed.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612